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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,964	04/15/2004	Kenneth T. Heruth	1023-360US01	8232
28863 7590 01/02/2008 SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125			EXAMINER SMITH, FANGEMONIQUE A	
			ART UNIT 3736	PAPER NUMBER
			NOTIFICATION DATE 01/02/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@ssiplaw.com

Office Action Summary

Application No.

10/825,964

Applicant(s)

HERUTH ET AL.

Examiner

Fangemonique Smith

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-33,35-45,53-62,72 and 73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-33,35-45,53-62,72 and 73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Request for Continued Examination filed on November 7, 2007. The Examiner acknowledges the cancellation of claims 1-18, 34, 46-52 and 63-71; the amendment of claims 19, 39 and 53-57; and the addition of claims 72 and 73. Claims 19-33, 35-45, 53-62, 72 and 73 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 19-33, 35-45, 53-62, 72 and 73 are rejected under 35 U.S.C. 102(e) as being anticipated by Hatlestad et al. (U.S. Patent Application Publication Number 2005/0042589 A1). In regard to claims 19-33, 35-45, 53-62, 72 and 73, Hatlestad et al. disclose a sleep quality data collection and evaluation device which assess sleep quality based on detected physiological or non-physiological patient conditions. The medical device disclosed by Hatlestad et al. comprises a plurality of sensors which generate a signal as a function of at least one physiological parameter of a patient (paragraphs [0066]-[0070]). The device also includes an implantable device and a microprocessor with memory. The microprocessor monitors a plurality of physiological parameters of the patient based on the signals output by the sensors (paragraphs

[0066]-[0082]). The Hatlestad et al. device determines a value of a sleep metric that indicates a probability of the patient being asleep based on the physiological parameters. The value of the sleep metric is a percentage which ranges between about 0 to about 1 (paragraphs [0135]-[0162]). Hatlestad et al. disclose using the device to monitor respiratory rates and blood oxygen saturation levels of a patient (paragraphs [0062]-[0081]). The microprocessor disclosed by Hatlestad et al. determines variability and a mean value of at least one of the physiological parameters and determines sleep metric values from the information gathered (paragraphs [0135]-[0162]). The system then determines a value of an overall sleep metric based the values of the plurality of sleep metrics and determines the value of the overall sleep metric by averaging the values of the plurality of sleep metrics (paragraphs [0090]-[0103]). Hatlestad et al. further disclose the device including a memory used to store threshold values, wherein the processor compares the value of the sleep metrics to the threshold values and determines whether the patient is asleep based on the comparison (paragraphs [0080]-[0103]). Hatlestad et al. disclose a means for monitoring a plurality of physiological parameters of a patient and a means for determining a value of a sleep metric indicates based on the physiological parameters. The Hatlestad et al. device further includes a means for generating at least one signal as a function of the physiological parameters, wherein the means for monitoring comprises means for monitoring the physiological parameters based on the signal. The means for determining a sleep metric expressed by Hatlestad et al. comprises means for determining a value for each of a plurality of sleep metrics, each of the plurality of values determined based on a respective one of the physiological parameters (paragraphs [0135]-[0162]). The device determines a value of a sleep metric by determining a value of an overall sleep metric based the values of the plurality of sleep

metrics and a comparison of the value of the sleep metric to a threshold value. Additionally, Hatlestad et al. disclose a means for delivering a therapy to the patient and means for controlling delivery of a therapy to the patient by the therapy delivery means based on the determination of whether the patient is asleep. The Hatlestad et al. device has a storage mechanism for storing values to access at a later time. Hatlestad et al. suggest the implantable medical device may be an implantable neurostimulator (paragraph [0059]).

Response to Arguments

4. Applicant argues the prior art references fail to disclose an implantable device, which returns a non-binary sleep metric indicating a probability of a patient being asleep. Applicant's arguments filed November 7, 2007 with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

A handwritten signature in black ink, appearing to read "M. J. [unclear]", is located in the lower right quadrant of the page.